

REMARKS

This responds to the Office Action mailed on February 22, 2008.

Claims 1 and 27 are amended, claims 25 and 30 are canceled, and no claims are added; as a result, claims 1, 4, 7-22, 27-29 and 31 are now pending in this application.

§112 Rejection of the Claims

Claims 27 and 29 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate description. Applicant believes the rejection is overcome by amendment and/or argument.

Claim 27 is amended to recite “wherein said dapsone is applied once a day.” The Examiner stated that once a day application is explicitly supported by the specification. Applicant notes that this should not be interpreted as a limiting amendment. Applicant believes that the phrases “no more than once a day” and “once a day” are equivalent. The specification discloses daily application (paragraph [0042] and Examples 1, 2 and 3), whether it be once daily, twice daily, or more frequently. There is no disclosure of less frequent administration, such as once weekly or once monthly. Additionally, those of skill in the art would readily understand that effective topical treatment of acne cannot be achieved with less than daily administration in the context of the instant invention. Thus, “no more than once a day” and “once a day” are equivalent. Withdrawal of the rejection of claim 27 under 35 U.S.C. § 112(1), written description, is respectfully requested.

Regarding the claim 29 limitation “wherein the efficacy for treating non-inflammatory acne is inverse to the efficacy for treating inflammatory acne,” the Examiner alleged that the limitation is not supported by the specification because “...applicants nowhere (including the data in Table 1) mention the relationship between treating non-inflammatory acne and its effect on the number of inflammatory acne lesions.”

The Examiner is respectfully requested to consider the guidance provided by the court in In re Wertheim, 541 F.2d 257 (CCPA 1976):

The PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of literal support alone were enough to support a rejection under § 112, then the statement of In re Lukach, supra, 442 F.2d at 969, 58 CCPA at 1235, 169 USPQ at 796, that "the invention claimed does not have to be described *in ipso verbis* in order to satisfy the description requirement of § 112," is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not *in ipso verbis* is insufficient.

As the court's opinion points out, an *in ipso verbis* recitation of the inverse efficacy of dapsone for treating non-inflammatory acne and inflammatory acne is not required. One of skill in the art would easily recognize this effect in the first data set of Table 1. Once daily dosing of 1% dapsone causes the least percent reduction of inflammatory lesions (13%) while the same dosing causes the greatest percent reduction of non-inflammatory lesions (53%). This inverse efficacy is immediately clear upon consideration of Table 1; thus, a sufficient description is provided.

The Examiner alleged that "...the specification does not clearly disclose to the skilled artisan that the inventors considered the inverse relationship to be part of their invention because other than the results on Table 1 applicants have not described such a relationship and the newly added limitation is picked from the general disclosure."

Applicant responds that MPEP 2163.02 states that an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). The descriptive means of the Table 1 data are sufficient to cause one of skill in the art to readily and immediately appreciate the possession of the claimed inverse relationship.

Third, Applicant has made clear throughout the instant specification that non-inflammatory acne and inflammatory acne are separate and distinct conditions (see paragraphs [0004]-[0007], [0012] and [0016]). Indeed, Applicant analyzed inflammatory and non-inflammatory acne separately in Example 2 and showed different effects of dapsone. This inverse efficacy shown in Table 1 and recited in claim 29 is a clear and important distinction between the two types of acne that corresponds clearly with the remaining disclosure of the specification. Thus, the specification conveys with clarity to those skilled in the art that

Applicant was in possession of the invention in claim 29 as of the filing date. Withdrawal of the rejection under 35 U.S.C. § 112(1), written description, is respectfully requested.

Claims 1, 4, 7-22 and 30 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claim 30 is canceled. Claim 1 is amended to recite "A method for treating non-inflammatory acne..." Claims 4 and 7-22 depend from claim 1 and thus include every limitation of claim 1. Applicant respectfully asserts that the amendment to claim 1 and the cancellation of claim 30 do not indicate that a number of non-inflammatory acne lesions are *not* reduced by topically applying the claimed dermatological composition. The amendments were made only to further prosecution, because reducing a number of non-inflammatory lesions and treating non-inflammatory acne are redundant. As stated in the instant specification at paragraph [0014], "As used herein, the term "treat", "treatment", or "treating" refers to the reduction in number and/or severity of individual acne lesions, prevention of the development of acne lesions, or global improvement in the appearance of acne lesions." Additionally, paragraph [0016] states, "However, our experimental data demonstrates that the number of non-inflammatory acne lesions are reduced as a result of treatment with topical dapsone." Thus, reducing a number of non-inflammatory acne lesions and treatment of non-inflammatory acne have the same meaning, and no subject matter has been eliminated by way of the claim amendments. Withdrawal of this rejection is respectfully requested.

§102 Rejection of the Claims

Claims 1, 4, 7, 13, 14, 20, 21, 25 and 27-31 were rejected under 35 U.S.C. § 102(b) as being anticipated by US 6,060,085 ('085) to Osborne or US 5,863,560 ('560) to Osborne (as evidenced by Russell, AFP, 2000).

Osborne '085 is a continuation of Osborne '560. In order to simplify the arguments below, Applicant will refer only to Osborne, but the arguments apply to both Osborne '560 and Osborne '085.

The Examiner has maintained the 35 U.S.C. § 102(b) rejection of claims 1, 4, 7, 13, 14, 20, 21, and 25 and has applied the same rejection to added claims 27-31. The Examiner has concluded that both inflammatory and non-inflammatory lesions are inherent to the acne

described in the teachings of Osborne and therefore the claimed method of reducing the number of non-inflammatory lesions and the treatment of non-inflammatory lesions of acne with dapsone is inherent to the teachings of Osborne.

Applicant respectfully asserts that the Examiner's theory of inherency is misapplied. First, Applicant reiterates that the patent law on inherency relies on the fundamental, but not articulated, presumption of actual use. Because there was no actual use of Osborne's topical dapsone in treating conditions of any kind, Osborne does not inherently anticipate the use of dapsone in methods of treating non-inflammatory acne. Second, in the context of actual use, Applicant reiterates that anticipation cannot attach because the treatment of non-inflammatory acne would not necessarily occur each and every time the prior art dapsone were used to treat inflammatory acne. Applicant will further elaborate on these arguments below.

It remains Applicant's position that the patent law on inherency generally relies on a fundamental, but not articulated, presumption of actual use. As discussed previously, the case law (including *In re May*, *In re Crish*, *In re Best*, and *In re Cruciferous Sprout Litigation*) supports this position. Although anticipation was upheld in these cases, Applicant points out that the compositions or methods claimed in each instance had actually been used. In contrast, Osborne's topical dapsone was never actually used to treat any form of acne, nor any other ailment. The formulation was merely applied to the skin of cadavers to test its permeation and retention abilities; no conditions were treated by this application to the skin. It would thus be impossible for Osborne's method of use of dapsone to inherently treat non-inflammatory acne, since until the instant application dapsone had never before been applied to living skin for use in treating any type of ailment.

Additionally, because an inherent feature must be present every time the prior art method or composition is used (see Donald S. Chisum, CHISUM ON PATENTS § 3.03[2][b], 2006), it would be impossible to conclude that Osborne's topical dapsone could inherently treat non-inflammatory acne. An anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). The topical dapsone of Osborne was never actually used in

treatment of inflammatory acne or any other skin condition; thus, it would be impossible for non-inflammatory acne to be necessarily treated each and every time the prior art dapsone were used, especially when applied to cadaver skin, as was performed in Osborne. In other words, non-inflammatory acne was not necessarily treated each and every time the dapsone of Osborne were used because no skin condition was ever actually treated. Rather, the dapsone of Osborne was applied to cadaver skin to test for permeability and retention properties. Thus, inherent anticipation cannot attach. Applicant thus respectfully submits that inherent anticipation of the use of topical dapsone to treat non-inflammatory acne cannot be found without the real and necessary element of actual use in Osborne.

In rejecting claims 27-31, the Examiner again alleged that because Russell teaches that acne is usually a mixture of both inflammatory and non-inflammatory lesions, non-inflammatory lesions are inherent to the acne described in Osborne. Applicant has previously argued, and reiterates here, that simply because both forms of acne are usually present, does not mean that they always exist together, and does not lead to the conclusion that a treatment which is successful in reducing one form of acne necessarily succeeds in reducing the other form. Indeed, those of skill in the art know that the two types of acne require drastically different treatments and that antibiotics, which are indicated for use in treating inflammatory acne, are counter-indicated for the treatment of non-inflammatory acne (see the 37 C.F.R. §1.132 declaration of Robert Lathrop).

It was well known in the art at the time of Osborne, and is still common practice today, that topical antibiotics are used to reduce inflammatory acne, not non-inflammatory acne. On page 62 of "Acne: A Review of Optimum Treatment" (Drugs 48(1): 59-70, 1994), Sykes states that "Topical antibiotics are very useful in the treatment of mild to moderate inflammatory acne vulgaris, but probably have no role in treating the comedonal phase of the disease." Russell also shows (Figure 5, Algorithm for the management of acne) that antibiotics are used for treating inflammatory lesions and mixed lesions, but not non-inflammatory comedonal lesions. Finally, Osborne specifically discusses the use of antimicrobials and anti-inflammatory agents (including dapsone, see Column 5), but does not disclose non-inflammatory or comedonal acne (as the Examiner acknowledges). Applicant stresses that antibiotics generally are known not to treat non-inflammatory comedonal lesions; consequently, a person of ordinary skill in the art would

expect that topical antibiotic dapsone would fail in reducing non-inflammatory acne lesions.

Thus, inherency has not been established.

Claim 30 is cancelled. Regarding claim 31, Applicant asserts that the limitation of “identifying non-inflammatory acne” cannot be inherent to the disclosure of Osborne. As discussed previously, Osborne does not disclose non-inflammatory acne; thus, this active step requiring conscious identification of the non-inflammatory acne cannot be anticipated by Osborne.

In sum, Applicant respectfully asserts that because there was no actual use of Osborne’s topical dapsone in treating conditions of any kind, Osborne does not inherently anticipate the use of dapsone for treating non-inflammatory acne. Additionally, in the context of actual use, Applicant reiterates that anticipation cannot attach because the treatment of non-inflammatory acne would not necessarily occur each and every time the prior art dapsone were used to treat inflammatory acne. This is especially true given that inflammatory acne and non-inflammatory acne are separate and distinct conditions that do not always co-exist. Inherent anticipation of the claimed methods cannot be found, and Applicant respectfully requests withdrawal of this rejection.

§103 Rejection of the Claims

Claims 8-12, 15-19 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,060,085 in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21, 25 and 27-31 above, and further in view of US 6,200,964 to Singleton et al OR over US 5,863,560 (‘560) in view of Russell as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of Russell and US 6,200,964 to Singleton et al. Claims 25 and 30 are cancelled.

The Examiner has maintained this rejection despite Applicant’s arguments that the inherency issue was improperly carried over from the 35 U.S.C. § 102(b) rejection. The inherency doctrine has no place in the determination of the obviousness of a new use of an old compound (*In re Shetty*, 195 USPQ 753 (C.C.P.A. 1977) and *In re Dillon*, 13 USPQ2d 1335, 1348 (Fed. Cir. 1989)), and Applicant remains steadfast in the position that the treatment of non-inflammatory acne is not inherent to Osborne. Thus, the rejection under 35 U.S.C. § 103(a) is improper.

The Examiner has maintained the argument that the combination of references cited for the 35 U.S.C. § 103(a) rejection are not directed to the claimed method, but are instead directed to the claimed forms of the composition (i.e., cream, lotion, spray, etc.) and thus it would have been obvious to prepare the dapsone compositions of Osborne in these topical forms with an expectation to achieve the desired treatment of both types of acne lesions. Applicant respectfully disagrees with this conclusion.

Applicant contends that this is an improper rejection, because the claims at issue are method claims, not composition claims. In the rejected claims, Applicant is not attempting to claim the compositions themselves, but rather is claiming the methods using the compositions. Each of the rejected claims depends from claim 1, which recites a method for reducing non-inflammatory acne lesions with dapsone. Dependent claims include all of the limitations of the claims from which they depend (see MPEP 608.01(n)); thus, the method of treatment cannot be ignored in these rejections under 35 U.S.C. § 103. Applicant reminds the Examiner that the patentability of a new use for an "old" or known composition is a statutory mandate that has been relied on by the C.C.P.A. and the Federal Circuit. "See 35 U.S.C. § 101 (2000), identifying as patentable 'any new and useful improvements' of a process, machine, manufacture, etc); *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (principles of inherency do not prohibit a process patent for a new use of an old structure)." *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005).

The only explanation provided by the Examiner regarding how Osborne, Russell and Singleton form the basis of the § 103 rejection is that Russell and Singleton disclose different skin types, creams, lotions, and sprays, so it therefore would have been obvious to prepare dapsone in those formulations with an expectation to achieve the desired treatment of acne lesions (both types). The only way to reach this expectation of treating both types of acne lesions with dapsone is to implicitly carry the inherency conclusion over from the 35 U.S.C. § 102 analysis of Osborne. No other basis for the § 103 rejection of the claimed method of treating non-inflammatory acne has been provided by the Examiner. As stated above, inherency is an improper basis for a 35 U.S.C. § 103 rejection.

As Applicant has previously shown, the only "expectation" a person of skill in the art would have regarding the treatment of non-inflammatory acne with dapsone is that it would not

work. The references teach away from the claimed invention. Applicant again refers to the declaration of Robert Lathrop and the disclosure of Sykes in reiterating the well known fact that anti-microbials are counter-indicated for the treatment of non-inflammatory acne. Thus, the expectation to achieve the treatment of both types of acne with the topical dapsone of Osborne must result from the Examiner's improper application of the inherency doctrine. Because the theory of inherency fails, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 103.

In summary, the Examiner has continued to rely on a theory of inherency for each of her arguments in rejecting the claims of the instant application under 35 U.S.C. §102 and §103. The entire case stands or falls on whether the dapsone of Osborne '085 and '560 inherently possesses the ability to reduce non-inflammatory acne. Applicant first submits that because the dapsone method of Osborne was never actually used to treat any kind of condition in a living being, this method cannot be said to inherently possess activity useful in the treatment of non-inflammatory acne. In the context of these arguments, Applicant additionally contends that because the treatment of non-inflammatory acne would not necessarily occur each and every time the prior art dapsone were used, inherent anticipation cannot attach. Consequently, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 102 and 35 U.S.C. § 103.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 12 day of August 2008.

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